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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,948	05/01/2007	Thomas Nissl	37621/51901	7923

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MERIT MEDICAL SYSTEMS, INC.  
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SALT LAKE CITY, UT 84111

EXAMINER
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SHIPMON, TIFFANY P

ART UNIT	PAPER NUMBER
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3738

MAIL DATE	DELIVERY MODE
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06/24/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/573,948	<b>Applicant(s)</b> NISSL ET AL.	
	<b>Examiner</b> TIFFANY SHIPMON	<b>Art Unit</b> 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 March 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Response to Arguments***

1. Applicant's arguments with respect to claims 1-11 have been considered but are moot in view of the new ground(s) of rejection. Applicant argues that the connector of Giantureo et al. does not securely couple the thread ends inside the tubular frame, however, as modified by Bolea et al. in which a lasso (ends of a loop are securely coupled and thus form the loop) inside of the frame element in order to be removed from the body. Applicant argues that the thread of Giantureo et al. does not teach a thread partially encircling the tubular support frame. However, because the thread of Giantureo et al. is woven into and out of the eyes on the end portions of the annular frame member, it is in fact partially encircling the frame every time the thread is woven out of the "eye". Applicant also argues that the Landau et al. reference does not teach or suggest a connector positioned inside the tubular frame. The Landau et al. discloses connectors that connect portions of the strut together and can comprise a marker material. Landau et al. is used as a teaching that a marker material can be used in order to see the positioning, as the thread ends are also being "connected" as the struts are in Landau et al.

### ***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-7, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giantureo et al. (US 5,035,706) in view of Bolea et al. (US 2002/0188344) .

Referring to claim 1, Giantureo et al. discloses a removable stent comprising: a plurality of annular segments arranged axially successively and interconnected to form a tubular support frame(Fig. 6); one or more deflection elements coupled to at least one of the plurality of annular segments and positioned on a circumference of the tubular support frame(eyes, 20); a thread at least partially encircling the tubular support frame outside of the circumference of the tubular support frame, the thread having a first end and second end that are each guided by one of the one or more deflection elements from the outside of the tubular support frame into a position inside the tubular support frame(the thread 40, passes through the eyes of the that are located on the circumference of the stent; therefore going from the outside of the frame to a position inside the frame); a connector(70) positioned adjacent the tubular support frame to couple together the first and second thread ends, wherein displacement of the connector relative to the stent along a longitudinal axis of the stent results in contraction of at least two of the plurality of annular segments(the annular segments are interconnected, therefore as the end of one annular segment is compressed, the it causes the other annular segments to contract along with the sheath in order to remove the stent). Giantureo et al. lacks a detailed description of the connector being positioned inside the tubular support frame, and the connector securely coupling the thread ends. However, Bolea et al. teaches a stent connected to a diameter controlling

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lasso(80) via holding loops (170) with the lasso(80) being positioned inside the stent(paragraphs 49-51). It would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the thread (40) of Giantureo et al. to be connected inside the stent as taught by Bolea et al. as an alternative structure for controlling the diameter. Further, by moving the connector of the thread inside the stent, it will move the connector as well.

4. Referring to claim 2, Giantureo et al. discloses, wherein the first and second ends of the thread are capable of being guided by the same deflection element (the end of the thread portions are capable of being woven through the same deflection element).

5. Referring to claim 3, Giantureo et al. discloses wherein the first end of the thread is guided by a first of the one or more deflection elements and the second end of the thread is guided by a second of the one or more deflection elements, wherein the first deflection element and second deflection element are positioned at an interval from one another (Fig. 10A, item 56).

6. Referring to claim 4, Giantureo et al. discloses wherein the one or more deflection elements are provided on an end-side annular segment, viewed in the direction of the longitudinal axis of the stent (Fig. 10A eyes positioned on the end of the stent).

7. Referring to claim 5, Giantureo et al. discloses wherein the one or more deflection elements are positioned on an inner side, facing the middle of the stent, of the annular segment(eyes are placed on both sides of the annular rings, therefore they are

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placed on an inner side, facing the “middle” of the stent when other annular segments are interconnected).

8. Referring to claim 6, Giantureo et al. discloses, wherein the first deflection element is arranged on the inner side, facing the middle of the stent, of an annular segment and the second deflection element is arranged on the outer side of the annular segment (The deflection elements(eyes) are arranged on the circumference of the annular segment. Since the annular segment is 3-dimensional it is inherent that the deflection element is arranged on the inner and outer side of the annular segment).

9. Referring to claim 7, Giantureo teaches a stent with annular segments capable of comprising multiple annular segments (Fig. 6) wherein the first deflection element is provided on an end-side annular segment, viewed in the direction of the longitudinal axis of the stent(see Fig. 6), and a second deflection element is provided an adjacent annular segment, wherein the thread is positioned inside the first deflection element (see Fig. 7A). Giantureo et al. does not expressly teach the second deflection element adjacent to the first annular segment. However, it would have been obvious to a person of ordinary skill in the time of the invention to modify the embodiment of the Fig. 7A to include the multiple annular segments, thus adjacent segments of Fig. 6 (where the adjacent annular segments provide adjacent deflection elements in order to expand the stent).

10. Referring to claim 9, Giantureo et al. discloses the stent further comprising additional guide elements coupled to the tubular support frame (see Fig. 10A multiple guide elements).

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11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Giantureo et al. in view of Bolea et al. as applied to claim 1 above, and further in view of Landau et al. (US 20020058986). Giantureo et al. does not expressly disclose the connector consisting of a material visible in x-rays. Landau et al. teaches a stent in the same field of endeavor with connectors that may be formed from a radiopaque material for the purpose of identifying the location of the a portion of the prosthesis (paragraph 169, the connector is used to couple together struts of the invention). Therefore it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the connectors of Giantureo et al. (which couples the thread together) to include radiopaque material in order to be able to identify a portion of the prosthesis.

12. Claims 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giantureo et al. in view of Bolea et al. as applied to claim 1 above, and further in view of Cox (US Patent No. 6, 375,676). Referring to claims 10-11, Giantureo et al. discloses annular strut segments but does not expressly disclose the annular segments being connected by connector struts or that the each connector strut connects to a longitudinal section aligned to a U shaped strut pattern. Cox teaches in the same field of endeavor a tubular stent wherein the annular segments are formed by struts that follow one another in an endless, corrugated manner (Fig. 9) and that adjacent annular segments are coupled by connector struts (13) and wherein each connector strut comprises a longitudinal section running substantially parallel to the longitudinal axis of the stent (76) and comprises a strut section aligned transversely to the latter and configured in a U shape (74) for the purpose of providing an even distribution of forces

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on the stent. Therefore it would have been obvious to a person of ordinary skill in the art to have the annular segments being connected to a connector with a longitudinal section aligned to a U shaped strut pattern as taught in Cox in order to allow for the even distribution of forces on the stent.

### ***Conclusion***

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TIFFANY SHIPMON whose telephone number is (571)270-1448. The examiner can normally be reached on Monday thru Friday, 8AM-5 PM, Est., alternate Fridays.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/T. S./

Examiner, Art Unit 3738

/Corrine M McDermott/

Supervisory Patent Examiner, Art Unit 3738

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